REMARKS

Per the above amendments, which are mostly in accord with the Examiner's suggestions, and the discussions to follow, Applicant has in the main overcome the 35 USC 112 first paragraph rejections. With regard to the term "quinolone- or naphthyridonecarboxylic acid, the amendment is being made to clarify the Examiner's perceived ambiguity in order to expedite prosecution. The only outstanding 112, is the rejection of the claims on the grounds that the term "insoluble matrix" is indefinite because it is unclear as to which solvents the quinolone- or naphthyridonecarboxylic acid is insoluble. Applicant traverses the rejection because the term as defined in the application would be clear to the skilled artisan. Thus the issue is whether the skilled artisan would be able to ascertain the metes and bounds of the claims reciting the term insoluble matrix.

In determining definiteness, it seems to Applicant that the factual inquiry should be into the relationship between quinolone or naphthyridonecarboxylic acid and the insoluble matrix. In this regard, Applicant directs the Examiner's attention to the captioned application at page 4, line 3 through line 7, which describes the relationship and illustrate the insoluble matrix as follows:

> "Illustrative but non-limiting examples of the insoluble matrix can be selected from the group consisting of shellac, polyvinyl alcohol, poly (D,L-lactic-co glycolic) acid, sugars, and polyethylene glycol, which is preferably of high molecular weight. Preferred herein is shellac, especially in form of flakes."

From the description including the above examples, the skilled artisan can ascertain the insoluble matrix. Therefore, the claims comply with the requirements of 35 USC 112, second paragraph.

Claims 1-2 and 6-8 are rejected under 35 USC 102(b) as being anticipated by Lange et al. (US 5,152,986) or Vetter et al. (US 5,808,076). The rejection is based on the grounds that:

> "Lange et al disclose a solid orally administered medicament preparation comprising quinolonecarboxylic acid derivatives, polyethylene glycols and polyvinyl alcohols used in feedstuffs for animals for the improvement of masking flavor and intake of the composition ..."

Applicant traverses the rejection because Lange et al does not disclose solid phase dispersion. Hence the issue is whether, Lange et al teaches the elements of

the claim in the same arrangement as the claims. In re Bond 15 USPQ2d 1566 (Fed. Cir. 1990). Fairly read, Lange et al relates to a combination of quinolonecarboxylic acid with ion exchange resin. No where does Lang et al teaches a solid phase dispersion of quinolonecarboxylic acid and an insoluble matrix. Therefore, Lange et al does not anticipate the claims.

Claims 1-2 and 6-8 stand rejected under 35 USC 102(b) as being anticipated by Vetter et al on grounds that:

> "Vetter et al. disclose a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter flavoring and fight bacterial infections in humans and animals ..."

Here again, Applicant traverses the rejection because Vetter et al does not disclose solid phase dispersion. Hence, the issue is whether Vetter et al teaches the elements of the claim in the same arrangement as the claims. In re Bond 15 USPQ2d 1566 (Fed. Cir. 1990). Fairly read, Vetter et al relates to the combination of quinolonecarboxylic acid with embonic acid. No where does Vetter et al teach a solid phase dispersion of quinolonecarboxylic acid and an insoluble matrix. Therefore, Vetter et al does not anticipate the claims.

Claims 3-5 stand rejected under 35 USC 103(a) as being unpatentable over Lange et al or Vetter et al in view of Pollinger et al (US Pat 5,695,784). The rejection is based on the grounds that:

> "It would have been obvious to one of ordinary skill in the art at the time the invention was made to use quinolone- or naphthyridonecarboxylic acids to mask ill-flavored compositions in feed or food stuff applications, with the expected result of obtaining an edible, improved tasting, therapeutic composition for the treatment of bacterial infections in humans and animals."

Applicant traverses the rejection for failure to present a case of prima facie obviousness because the references lack any basis for modification to a solid phase dispersion of the subject active ingredients and an insoluble matrix with a reasonable expectation of success. It seems to Applicant that this failure to present a prima facie case is at least due to the failure to recognize the significant difference between references and the claims as discussed above. That is the failure of the references, including Pollinger et al, to teach a solid phase dispersion comprising the active ingredient and an insoluble matrix. The Examiner has made no finding of fact

which would have led the skilled artisan to the belief that one can make the claim-recited a solid phase dispersion. To be sure, the references have mentioned some of the ingredients of Applicant's claims. But the mere mention of them does suggest that they can be combined in the manner of the claims, in the absence of some basis in the references for suggesting the modification with a reasonable expectation of success. Absent a showing of such basis, the references fail to support a prima facie case of obviousness.

In view of the foregoing amendments and discussions, Applicants submit that the claims in the application are patentably distinct and pray for their allowance.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE:

IN THE SPECIFICATION:

At page 2, please delete the paragraph beginning at line 12, and ending on line 21, and replace it with the following:

--It has surprisingly been found that the solid phase dispersion in accordance with this invention provides greatly reduced quinolone- or naphthyridonecarboxylic acid particle size. It has also been found that the dispersion provides acceptable solubility of the quinolone- or naphthyridonecarboxylic acid. It has also been found that the dispersion provides controlled release of the quinolone- or naphthyridonecarboxylic acid, which can be administered orally without any problems even to animals which will normally refuse formulations containing quinolone- or naphthyridone-carboxylic acid owing to their bitter taste. Unexpectedly, the solid phase dispersion has an outstanding acceptance when administered.--

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended). A solid phase dispersion comprising a quinolone<u>carboxylic acid</u>- or naphthyridonecarboxylic acid in an insoluble matrix.

2. (Amended). The dispersion according to Claim 1, wherein the insoluble matrix is selected from the group consisting of shellac, high molecular weight polyethylene glycol, polyvinyl alcohol, poly(D.L.-lactic co glycolic and sugars.

4. (Amended). The dispersion of Claim 1, wherein quinolone<u>carboxylic acid</u>- or naphthyridonecarboxylic acid and the insoluble matrix are in a ratio of 1:0.5 to 10.

5. (Amended). The dispersion of Claim 4, wherein quinolone<u>carboxylic acid</u>- or naphthyridonecarboxylic acid and the insoluble matrix are in a ratio of 1:5.

6. (Amended). A method of preparing a solid dispersion of a quinolonecarboxylic acid- or naphthyridonecarboxylic acid, comprising forming a hydrate of the quinolonecarboxylic acid- or naphthyridonecarboxylic acid, mixing quinolonecarboxylic acid- or naphthyridonecarboxylic acid with an insoluble matrix, heating the mixture until it flows, and micronizing the mixture.

8. (Amended). A process for improving animal uptake of quinolone- or naphthyridonecarboxylic acid comprising orally administering to the animal a solid phase dispersion of a quinolonecarboxylic acid- or naphthyridonecarboxylic acid and an insoluble matrix in an effective amount to mask the taste of the active agent.